What is in this leaflet

Please read this leaflet carefully before you start taking MONTELUKAST MYLAN.

This leaflet answers some common questions about MONTELUKAST MYLAN.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MONTELUKAST MYLAN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What MONTELUKAST MYLAN is used for

MONTELUKAST MYLAN is used to treat:

- asthma, including preventing asthma symptoms during the day and night. It also prevents the narrowing of airways triggered by exercise.
- seasonal and year-round allergies, including daytime and night time symptoms, including nasal congestion, runny nose, nasal itching, and sneezing; nasal congestion upon awakening, difficulty going to sleep, and night time awakenings; tearing, itchy, red, and puffy eyes.

MONTELUKAST MYLAN can be used in children 2 years of age and older, teenagers and adults.

MONTELUKAST MYLAN tablets are not used to treat an acute attack of asthma. If an acute attack occurs, follow your doctor’s instructions for that situation.

Asthma is a lung disease and has the following characteristics:

- narrowed airways causing breathing to become difficult.
- inflamed airways, which means the lining of airways become swollen.
- sensitive airways that react to many things, such as cigarette smoke, pollen, or cold air.

Symptoms of asthma include coughing, wheezing and chest tightness. Not all people with asthma wheeze. For some, coughing may be the only symptom of asthma. Symptoms often occur during the night or after exercise.

Seasonal allergies (also known as hay fever) are triggered by outdoor allergens such as airborne pollens from trees, grasses and weeds.

Year-round allergies may occur year-round and are generally triggered by indoor allergens such as dust mites, animal dander, and/or mould spores.

MONTELUKAST MYLAN belongs to a group of medicines called leukotriene receptor antagonists. It works by blocking substances in your lungs called leukotrienes that cause narrowing and swelling of airways. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks. Leukotrienes also cause allergy symptoms. Blocking leukotrienes improves allergic rhinitis (seasonal and year-round, also known as outdoor and indoor nasal allergies).

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor’s prescription.

This medicine is not addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you take MONTELUKAST MYLAN

When you must not take it

Do not take MONTELUKAST MYLAN if you have an allergy to:

- any medicine containing montelukast sodium.
- any of the ingredients listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not give this medicine to a child under the age of 2 years. Safety and effectiveness in children...
younger than 2 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it
Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. MONTELUKAST MYLAN has not been studied in pregnant women and it is not known if this medicine passes into breast milk. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking MONTELUKAST MYLAN.

Taking other medicines
Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking MONTELUKAST MYLAN.

Some medicines may affect the way other medicines work. In general, MONTELUKAST MYLAN does not interfere with other medicines that you may be taking. However, some medicines may affect how MONTELUKAST MYLAN works, or MONTELUKAST MYLAN may affect how your other medicines work.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take MONTELUKAST MYLAN

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Take MONTELUKAST MYLAN only when prescribed by your doctor.

For adults and teenagers 15 years and older, for the treatment of asthma, seasonal and year-round allergies, the dose is one 10 mg tablet taken daily.

For children 6 to 14 years old, for the treatment of asthma, seasonal and year-round allergies, the dose is one 5 mg chewable tablet taken daily.

For children 2 to 5 years old, for the treatment of asthma, seasonal and year-round allergies, the dose is one 4 mg chewable tablet taken daily.

Studies have shown that MONTELUKAST MYLAN does not affect the growth rate of children.

How to take it

MONTELUKAST MYLAN comes as three types of tablets:

- 10 mg tablets for adults and teenagers 15 years and older
- 5 mg chewable tablets for children 6-14 years old
- 4 mg chewable tablets for children 2 -5 years old

Swallow the 10 mg tablet whole with a glass of water.

Chew the 4 mg or 5 mg chewable tablet thoroughly and swallow.

When to take it

For patients with asthma, take MONTELUKAST MYLAN once a day in the evening. Taking your tablet at bedtime each day will have the best effect. It will also help you remember when to take the tablets.

For patients with allergic rhinitis, take MONTELUKAST MYLAN once a day as prescribed by your doctor. Taking it at the same time each day will help have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you. This medicine helps to control your condition but does not cure it. It is important to keep taking your MONTELUKAST MYLAN

If you forget to take it

Skip the dose you missed and take your next dose as usual. Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking MONTELUKAST MYLAN

Things you must do

Continue taking MONTELUKAST MYLAN every day as directed by your doctor, even if you have no asthma symptoms or if you have an asthma attack.

If your asthma gets worse while taking MONTELUKAST MYLAN, tell your doctor immediately.

If an acute attack of asthma occurs, follow your doctor’s instructions on what medicines to use to relieve the attack.

If you experience behaviour and mood-related changes while taking MONTELUKAST MYLAN, tell your doctor immediately.
If you become pregnant while taking MONTELUKAST MYLAN, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking MONTELUKAST MYLAN.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking MONTELUKAST MYLAN.

Things you must not do

Do not take MONTELUKAST MYLAN to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

MONTELUKAST MYLAN is not expected to affect your ability to drive a car or operate machinery.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much MONTELUKAST MYLAN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MONTELUKAST MYLAN. This medicine helps most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:
- headache,
- stomach pain,
- thirst.

In studies, these are the more common adverse effects of MONTELUKAST MYLAN. For the most part these have been mild and occurred as often in patients treated with MONTELUKAST MYLAN or placebo (a tablet containing no medicine).

Tell your doctor as soon as possible if you notice any of the following:
- upper respiratory infection,
- increased bleeding tendency, low blood platelet count,
- behaviour and mood related changes [agitation including aggressive behaviour or hostility, depression, disorientation, disturbances in attention, dream abnormalities, feeling anxious, hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, sleep walking, stuttering, suicidal thoughts and actions, tremor, uncontrolled muscle movements],
- dizziness, drowsiness, pins and needles/numbness,
- palpitations,
- nose bleed; swelling (inflammation) of the lungs,
- diarrhoea, dyspepsia, nausea, vomiting
- hepatitis,
- bruising, rash, and itching
- joint pain, muscle aches and muscle cramps,
- bedwetting in children,
- weakness/tiredness,
- swelling,
- fever.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:
- allergic reactions:
  - including swelling of the face, lips, tongue, and/or throat (which may cause trouble breathing or swallowing),
  - hives (severe and sudden onset of pinkish itchy swellings on the skin, also called nettle rash),
  - severe skin reactions that may occur without warning.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking MONTELUKAST MYLAN

Storage

Keep your tablets in the bottle until it is time to take them. If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry dark place where the temperature stays below 25°C.

Do not store MONTELUKAST MYLAN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.
Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal
If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

4 mg chewable tablet: A white to off-white coloured, oval, biconvex tablet debossed with “M” on one side and “MS1” on the other side.

5 mg chewable tablet: A white to off-white coloured, round, biconvex tablet debossed with “M” on one side and “MS2” on the other side.

10 mg film coated tablet: A blue film-coated, round bi-convex beveled edge shaped tablet debossed with “MO” over “10” on one side and “M” on the reverse.

Ingredients

Active ingredient(s):
- MONTELUKAST MYLAN 4 mg chewable tablet contains 4 mg montelukast.
- MONTELUKAST MYLAN 5 mg chewable tablet contains 5 mg montelukast.
- MONTELUKAST MYLAN 10 mg film coated tablet contains 10 mg montelukast.

Inactive ingredient(s):
MONTELUKAST MYLAN 4 mg and 5 mg chewable tablets also contains:
- mannitol,
- microcrystalline cellulose,
- croscarmellose sodium,
- aspartame (E951),
- colloidal anhydrous silica,
- magnesium stearate,
- sodium lauryl sulfate,
- The cherry flavour (501027 AP 0551) contains:
  - maize maltodextrin,
  - benzyl alcohol (E1519),
  - triethyl citrate (E1505).

MONTELUKAST MYLAN 10 mg film coated tablets also contains:
- microcrystalline cellulose,
- mannitol,
- croscarmellose sodium,
- magnesium stearate,
- sodium laurylsulfate
- silica colloidal anhydrous.
- The film coating consists of:
  - polydextrose,
  - titanium dioxide,
  - triacetin,
  - indigo carmine aluminium lake (E132),
  - macrogol 400,
  - sunset yellow aluminium lake (E110),
  - macrogol 8000.

This medicine does not contain lactose or gluten.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

MONTELUKAST MYLAN is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: (09) 579 2792

Date of Preparation

22 May 2019
(Based on datasheet dated 22 May 2019)